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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,535	03/06/2007	Justin Wong	PP019155.0004	7039

27476 7590 08/27/2009

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EXAMINER	
YAO, LEI	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
08/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,535	WONG ET AL.	
	Examiner	Art Unit	
	LEI YAO	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1 claim(s) 1-12, 16-26, drawn to a method of identifying an agent capable of inhibiting carbonic anhydrase activity of human CA IX polypeptide of SEQ ID NO: 2 or homologous thereof. (claims 1-12 read on antibody and claims 16-26 read on peptide or small molecule).

Group 2 claim(s) 13-15, 28, 32, 34-35, drawn to a method of inhibiting proliferation of neoplastic cells in a mammal comprising administering to said mammal a therapeutically effective dose of an agent that inhibit carbonic anhydrase activity.

Group 3 claim(s) 27, 29-31, 36-38, drawn to an inhibitor or an antibody to carbonic anhydrase activity of a CA IX polypeptide that has been identified in the method of group 1 and a composition thereof.

Group 4 claim(s) 33, drawn to a polypeptide consisting of the amino acid 135-414 of SEQ ID NO: 2.

Group 5, claim(s) 39-40, drawn to a method of assaying an antibody for the ability to inhibit carbonic anhydrase activity of a CA IX polypeptide.

Further election required under 35 U.S.C. 121:

A. anti-CA IX antibody
B. peptide (read on claim ,
C. peptoid,
D. small organic molecule.

This application is an internationally filed application filed under 35 U.S.C. 371 and is subject to the rules discussed under MPEP § 1850 (see the last paragraph under MPEP § 803.04, which references the appropriate section for internationally filed applications). Under Markush practice for international applications, the following criteria are required:

(A) the alternatives have a common property or activity and (B) a common core structure is present; or

(C) in cases where the core structure cannot be the unifying criteria, all alternatives must belong to the same recognized class of chemical compounds, that is, that the same result will be achieved when one member of the Markush group is substituted for another.

In the instant case, antibody, peptide and small organic molecule do not share a common core structure or activities. Therefore, they do not meet the criteria for (A) and (B). Also, the inhibitor does not meet criteria (C) because the same result is not achieved when using antibody for detecting the presence of the protein when and antibody is replace with a small molecule. Since the agents do not share the same or corresponding special technical feature under the specific criteria for Markush practice, the agents lack unity of invention and are not considered alternative species to one another. Therefore, applicant's proposed species election would be improper.

In order to be fully responsive, Applicant must elect one from Groups 1-5, one from Group A-D even though the requirement is traversed. Applicant is advised that

neither 1-5, nor A-D is species election requirements; rather, each of 1-5 and A-D is a restriction requirement.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (i).

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions

listed as Groups 1-5 do not relate to a single general inventive concept under PCT Rule 13.1 because, they lack the same or corresponding special technical features for the following reasons: The special technical feature of group 1 is considered to identify an antibody that inhibits the biological activity of CA IX protein. The special technical feature that links groups is considered to be antibody to CA IX of SEQ ID NO: 2, which has been disclosed by Zavada et al (US Patent, 6093548). Zavada et al disclose MN protein that is identical to the amino acids of SEQ ID NO: 2 as evidenced by sequence search result and disclose an antibody to the protein and the antibody has ability to inhibit the biological action of the protein (section: MN antibody, col 38+). Thus the special technical feature of group 1 as well as the special technical feature linking each of the groups is not a contribution over the prior art and thus does not constitute a special technical feature as defined by PCT Rule 13.2.

Election of Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a. cytotoxin, a therapeutic agent, or radioactive metal ion (claim 11).
b. amino acid at position: 226, 228, and 251 of SEQ ID NO: 2 (claim 6.
c. CHO, Sp2, or NS0 (claims 14-15).
d. COS, Chinese hamster ovary, NIH-3T3, 293 (claim 24).

If invention 1 is elected, Applicant is required, in reply to this action, to elect one single species from a, one from b, and one from d, to which the claims shall be restricted if no generic claim is finally held to be allowable. For example, elect cytotoxin from a, position at 251 from b, and COS cell from d.

If invention 2 is elected, Applicant is required, in reply to this action, to elect one single species from c.

The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each biological sample is prepared or collected in different way. The sequence of SEQ ID NO: 1 is expressed in one species, for example prostate tissue, may not be expressed in the other biological sample, such fecal matter or urine.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lei Yao/
Examiner, Art Unit 1642

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643